REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1, 4, 5, and 7-10 are pending and at issue. In this response, claim 1 is amended to specify the relationship between the Kex2-derived endoprotease required by the claim and Kex2; and claims 1, 4, and 5 are amended to correct informalities. Support for the amended claims can be found in the specification and claims as originally filed; for example, Kex2-derived endoproteases having at least about 90% homology to Kex2 are disclosed at page 5, lines 19-23. No new matter is added.

Rejection Under 35 U.S.C. § 102

Claims 1 and 7-10 have been rejected under 35 U.S.C. § 102(e) as anticipated by Barr et al., U.S. 5, 986,079. The Examiner contends that Barr et al. disclose the co-expression of Factor VII and PACE (furin) and that PACE can "reasonably be considered a variant of Kex2" (Office Action at page 3). This rejection is respectfully traversed.

PACE is unrelated to Kex2 both structurally and functionally. For example, the specificity of PACE is different from that of Kex2p; Kex2p cleaves at the carboxyl side of Lys-Arg, Arg-Arg, or Pro-Arg (see, present specification at page 3, line 30), whereas PACE cleaves at Arg-X-Lys/Arg-Arg, where X can be any amino acid (see, e.g., Rehemtulla et al., *Curr. Biol.* 3:560, 1992). Accordingly, Barr et al. cannot anticipate the present claims, which require the Kex2-derived endoprotease to exhibit (a) at least about 90% homology to yeast Kex2 and (b) Kex2 enzymatic activity. On this basis, it is respectfully submitted that this rejection has been overcome.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1, 5, and 7-10 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner contends that Applicants are claiming "a genus of endoproteases that have Kex2 activity" and that an insufficient number of such Kex2 variants are disclosed. This rejection is respectfully traversed.

The present specification clearly and unambiguously discloses the ability of Kex2 to cleave proFactor VII so as to produce single-chain Factor VII (itself a precursor to activated Factor VIIa). The specification further details four specific variants of Kex2 (two C-terminally truncated polypeptides, and each of those truncations with an ER-retention signal added.) Those of ordinary skill in the art would recognize that Applicants' invention requires Kex2 enzymatic activity (see above) and encompasses polypeptides that have undergone minor changes relative to Kex2 that do not substantially affect its Kex2 enzymatic activity. At the time of filing, it would have been well within the skill in the art to identify such Kex2-derived polypeptides exhibiting the required activity, and it is unclear why the Examiner continues to assert that the specification (in conjunction with what was known in the art) does not "support or illustrate the genus encompassed by the claim" (Office Action at page 5). To clarify this issue, in this response, claim 1 has been amended to specify that the Kex2-derived polypeptides that may be used in the present invention must be at least about 90% homologous to yeast Kex2. It is respectfully submitted on this basis that this rejection has been overcome and should be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 4, 5, and 7-10 have been rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In this response, claims 1 and 4 have been amended to correct the cited informalities.

On the basis of the above amendment and remarks, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

Date: Jan 23, 2003

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